

FDA finally approves Plan B—but with restrictions

Janice Hopkins Tanne *New York*

The US Food and Drug Administration has finally approved the emergency contraceptive Plan B for sale over the counter to women aged 18 or over.

Plan B is a two pill, high dose regimen of the oral contraceptive levonorgestrel. It is about 90% effective in preventing pregnancy when taken within 72 hours of unprotected sex.

Plan B will be available towards the end of the year at a cost of \$25 (£13; €20) to \$40. Women will have to request it from a pharmacist in a pharmacy that is licensed to sell it or from a health clinic. They will have to show government issued identification, such as a driver's licence, proving they are aged 18 or older. Younger women will

need a doctor's prescription.

Men aged 18 or older will also be able to buy the drug for their partner, a move that has raised concern that they may buy it for women under 18. It will not be sold at petrol stations or in convenience stores. The manufacturer, Barr Pharmaceuticals, will survey pharmacies to see that they follow the rules.

The FDA's acting commissioner, Andrew von Eschenbach, approved Plan B three days after President Bush said that he supported approval of the drug for women aged over 18, with prescription only access for younger women. In his approval letter Dr von Eschenbach noted that buyers of nicotine patches and some

other drugs already had to prove they were at least 18.

The approval came nearly three years after the FDA's own



Hillary Clinton blocked the FDA commissioner's appointment until Plan B was approved

expert advisory committees and professional staff recommended that the drug be available over the counter for women of all ages. Higher FDA officials, including the then commissioner, Lester Crawford, delayed a decision, and Dr Crawford later resigned.

Because of the FDA's delay in approving Plan B Senators Patty Murray of Washington state and Hillary Clinton of New York, both Democrats, had blocked the appointment of Dr von Eschenbach as permanent head of the FDA. When he approved the sale of Plan B the senators said they would cease blocking his nomination. The Senate will probably vote on the nomination this month when it returns from recess.



Derbyshire village wins court battle

Sophie Arie *London*

Residents of a former mining village in Derbyshire have won their battle for a greater say in whether a private company should be allowed to take over their local general practice.

The Appeal Court ruled that North Eastern Derbyshire Primary Care Trust had not consulted the residents of Langwith village before awarding UnitedHealth Europe the contract to provide GP services there and in the nearby village of Creswell.

In June the High Court judge Mr Justice Collins had ruled that although the consultation process may not have been adequate the company would probably have won the contract anyway (*BMJ* 2006;332:1469).

But last week Lord Justice May and Lord Justice Keene overturned that ruling.

"Probability is not enough. The simple fact is that the PCT [primary care trust] had a duty

to consult, and they did not properly perform it," said Lord Justice May.

He said that if consultation had taken place the trust "might well have been negotiating with another bidder."

The trust will now have to carry out a proper consultation process with the local patients' forum.

Pam Smith, 67, the local pensioner who had challenged the trust's decision, hailed the decision as a victory for "people power" against the government policy of allowing private companies to provide healthcare services at the level of general practice.

She said, "It was a real case of David and Goliath. I feel like I'm on a high. I would love to be a fly on [the health secretary] Patricia Hewitt's wall now. She keeps saying patients have a choice; well, we've made our choice. UnitedHealth would

only have taken profits. We will keep our NHS public, not private—that's what makes Britain unique."

Ms Smith and many other residents had hoped that a local doctor, Elizabeth Barrett, would take over the struggling surgery, arguing that UnitedHealth Europe, which is a subsidiary of one of the largest healthcare management companies in the United States, lacked the necessary understanding of the impoverished former mining community to provide the care it needs.

Dr Barrett's tender did not even make the primary care trust's shortlist, and on 23 December 2005 the trust announced that it had given the company "preferred provider" status.

Although no evidence was shown that the tendering process had been unfair, Ms Smith's complaint was that her views and those of other residents who shared her concerns were ignored.

Richard Stein, the lawyer representing Ms Smith, said he

hoped the case would guarantee that primary care trusts elsewhere in the country that are eager to contract private companies to provide primary care services made sure they listened to local concerns first.

UnitedHealth Europe did not confirm whether it would bid again to run the surgery in the new round of tendering. But the company, which is also interested in another Derbyshire surgery, in Normanton, reiterated its wish to find ways to provide primary care in the region.

"We believe that we can make a significant contribution in the region to reducing health inequalities," said Richard Smith, chief executive of the company and former editor of the *BMJ*.

A Department of Health spokesperson would not comment on the ruling, other than to say that the ruling had "no wider implications for the NHS or for government plans to introduce new providers in primary care." □